UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Honorable Joel Schneider, Magistrate Judge

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO RECONSIDER MTD ORDER 1 AND MTD OPINION 1, OR, IN THE ALTERNATIVE, FOR SECTION 1292(b) CERTIFICATION

TABLE OF CONTENTS

I. The Court Should Reconsider Its Opinion and Order 2

A. Legal Standard 3

B. The Court Overlooked and Misapprehended U.S. Supreme Court Precedent 3

C. The Court Overlooked the Weight of Authority in Confining *Buckman* Solely to "Fraud-on-the-FDA" Claims 7

D. The Court Erred in Holding the Act Does Not Expressly Preempt Plaintiffs' Claims Against Wholesalers and Pharmacies. 11

II. Alternatively, the Court Should Grant Section 1292(b) Certification 13

III. CONCLUSION 15

TABLE OF AUTHORITIES

Page(s)

Cases

Agee v. Alphatec Spine, Inc.,
No. 1:15-CV-750, 2017 WL 5706002 (S.D. Ohio Mar. 27, 2017) 9

Atay v. County of Maui,
842 F.3d 688 (9th Cir. 2016) 13

In re Baycol Prod. Litig.,
No. 04-3667, 2009 WL 7836091 (D. Minn. Feb. 13, 2009) 10

Borchenko v. L'Oreal USA, Inc.,
389 F.Supp.3d 769 (C.D. Cal. 2019) 8

Buckman v. Plaintiffs' Legal Committee,
531 U.S. 341 (2001) ..... *passim*

Chamber of Commerce of the United States v. Whiting,
563 U.S. 582 (2011) 6

Coventry Health Care of Mo., Inc. v. Nevils,
137 S. Ct. 1190 (2017) 13

In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.,
756 F.3d 917 (6th Cir. 2014) 9

Estate of Del Rosario by Gonzalez v. Paterson Police Dep't,
No. CV 14-5167, 2017 WL 1050572 (D.N.J. Mar. 20, 2017) 3

In re Depakote,
No. 12-CV-52-NJR-SCW, 2017 WL 4348052 (S.D. Ill. Sept. 28, 2017) 10

Desiano v. Warner-Lambert & Co.,
467 F.3d 85 (2d Cir. 2006) 7, 8, 10

In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.,
590 F.Supp.2d 1282 (C.D. Cal. 2008) 9

Evans v. Rich,
No. 5:13-CV-868-BO, 2014 WL 2535221 (E.D.N.C. June 5, 2014) 8, 9

Exela Pharma Scis., LLC v. Sandoz Inc.,
No. 1:19-CV-00318-MR, 2020 WL 5535026 (W.D.N.C. Sept. 15, 2020) 8

Farina v. Nokia, Inc.,
625 F.3d 97 (3d Cir. 2010) 13

In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II),
751 F.3d 150 (3d Cir. 2014) 10

Garcia v. Wyeth-Ayerst Laboratories,
385 F.3d 961 (6th Cir. 2004) 10

Golden v. N.J. Inst. of Tech.,
934 F.3d 302 (3d Cir. 2019) 9

Hughes v. Talen Energy Mktg., LLC,
136 S.Ct. 1288 (2016) 13

K.J. v. Greater Egg Harbor Reg'l High Sch. Dist. Bd. of Educ.,
No. CV 14-145, 2020 WL 3542305 (D.N.J. June 30, 2020) 3

Kansas v. Garcia,
140 S. Ct. 791 (2020) 6

Litgo New Jersey, Inc. v. Martin,
No.CIV. 06-2891 AET, 2011 WL 1134676 (D.N.J. Mar. 25, 2011) 15

Lofton v. McNeil Consumer & Specialty Pharmaceuticals,
672 F.3d 372 (5th Cir. 2012) 10

Loreto v. Procter & Gamble Co.,
515 F. App'x 576 (6th Cir. 2013) 8

Marsh v. Genentech, Inc.,
693 F.3d 546 (6th Cir. 2012) 10

In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.,
623 F.3d 1200 (8th Cir. 2010) 9, 10

In re Medtronic, Inc. Sprint Fidelis Leads Products Liab. Litig.,
592 F.Supp.2d 1147 (D. Minn. 2009) 9

Merck Sharp & Dohme Corp. v. Albrecht,
139 S. Ct. 1668 (2019) 5

Meyers v. Heffernan,
No. CIV.A. 12-2434 MLC, 2014 WL 7336792 (D.N.J. Dec. 22, 2014) 13, 14

Estate of Muniz v. Genentech, Inc.,
No. 1:11-CV-683, 2011 WL 5089289 (W.D. Mich. Oct. 26, 2011) 10

Mutual Pharmaceutical Co., Inc. v. Bartlett,
570 U.S. 472 (2013) 5, 6, 7, 10

Nexus Pharm., Inc. v. Quva Pharma, Inc.,
No. CV2007518CJCJDEX, 2020 WL 6498970 (C.D. Cal. Oct. 29, 2020) 9

Perez v. Nidek Co.,
711 F.3d 1109 (9th Cir. 2013) 9, 10

PLIVA, Inc. v. Mensing,
564 U.S. 604 (2011) ..... *passim*

Puerto Rico v. Franklin Cal. Tax-Free Trust,
136 S. Ct. 1938 (2016) 13

Riegel v. Medtronic, Inc.,
552 U.S. 312 (2008) 13

Riley v. Cordis Corp.,
625 F.Supp.2d 769 (D. Minn. 2009) 8

Shannon v. Johnson & Johnson,
No. 1:09 OE 40043, 2011 WL 2471921 (N.D. Ohio June 21, 2011) 10

Tigert v. Ranbaxy Pharmaceuticals, Inc.,
Civ. No. 12-00154, 2012 WL 6595806 (D.N.J. Dec. 18, 2012) 2, 7, 8, 10

In re Trasylol Prod. Liab. Litig.,
763 F. Supp. 2d 1312 (S.D. Fla. 2010) 10

Watson v. Air Methods Corp.,
870 F.3d 812 (8th Cir. 2017) 13

Wyeth v. Levine,
555 U.S. 555 (2009) ..... *passim*

In re: Zantac (Ranitidine) Products Liability Litigation,
Case No. 9:20-md-02924-RLR 1, 12

Statutes

28 U.S.C. § 1292(b) 2, 13, 15

Drug Supply Chain Security Act, 21 U.S.C. § 360eee-4 ..... *passim*

Food, Drug, and Cosmetic Act, 21 U.S.C. § 337(a) ..... *passim*

Other Authorities

Local Civil Rule 7.1(i) 3

INTRODUCTION

Defendants do not bring this motion lightly. Though Defendants are heedful of the Court's cautionary statements (Dec. 22, 2020 Tr. at 64:17-65:7), this is the first such motion Defendants have brought after two years of vigorously contested litigation. They do so now only because they respectfully believe the Court has misread federal preemption law and overlooked substantial superseding authority. Indeed, after two days of oral argument, this Court's sister district recently applied some of the same overlooked authority raised here in dismissing a number of similar claims directed to alleged nitrosamine-contaminated generic drugs. *See In re: Zantac (Ranitidine) Products Liability Litigation*, Case No. 9:20-md-02924-RLR, ECF Docs. 2512 & 2513 (S.D. Fla. Dec. 31, 2020) ("*In re Zantac*") (Exhibits A and B to the accompanying Certification of Aaron Van Nostrand, Esq.).

Defendants ask the Court to reconsider its MTD Opinion 1 (ECF Doc. 675) ("Opinion" or "Op.") and MTD Order 1 (ECF Doc. 676) ("Order") for three reasons:

First, the Opinion misstates that *Wyeth v. Levine*, 555 U.S. 555 (2009), is the "latest, single-most, on-point Supreme Court case for preemption of the FDCA in a pharmaceutical context." (Op. at 10). Defendants do not assert "impossibility" or "obstacle" preemption as addressed in *Wyeth*, but the prohibition against private party enforcement under Section 337(a) of the Food, Drug, and Cosmetic Act ("FDCA"), as recognized in *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341

(2001). *Wyeth* has no application here. And, as recognized in *In re Zantac*, post-*Wyeth* opinions require broader preemption in the context of generic drugs.

Second, the Opinion overlooks more recent and more predominant case law holding that *Buckman* is ***not*** limited to "fraud-on-the-FDA" claims, but rather encompasses all attempts at private enforcement of claims relying on the FDCA.

Third, the Opinion errs in its analysis of express preemption under the Drug Supply Chain Security Act, 21 U.S.C. § 360eee-4 (the "Act"). The Act preempts Plaintiffs' claims against the Wholesalers and Pharmacies because Plaintiffs seek to impose state law requirements more stringent than the Act. The Opinion also erroneously relies on an inapplicable presumption against preemption.

Defendants therefore respectfully ask the Court to set aside its disfavor for motions of this type and to reconsider its Opinion and Order or, in the alternative, to grant Defendants' request for Section 1292(b) certification.

ARGUMENT

I. The Court Should Reconsider Its Opinion and Order

Defendants moved to dismiss six of Plaintiffs' claims on the grounds that they are impermissible private attempts to enforce the FDCA as recognized in *Buckman*. (*See* ECF Doc. 520-3 at 17-27). The Opinion disagreed on two grounds: (1) *Wyeth* supersedes *Buckman* for "preemption of the FDCA in a pharmaceutical context"; and (2) this Court's ruling in *Tigert v. Ranbaxy Pharmaceuticals, Inc.*, Civ. No. 12-

00154, 2012 WL 6595806 (D.N.J. Dec. 18, 2012), limits *Buckman* to "fraud-on-the-FDA" claims. (Op. at 10-12). The Opinion overlooks precedent unequivocally distinguishing the separate *Wyeth* and *Buckman* lines of authority and making clear that *Buckman* preemption is not confined to the "fraud-on-the-FDA" context. As recognized in *Buckman*, 21 U.S.C. § 337(a) bars all private attempts to enforce legal requirements existing "solely by virtue" of the FDCA, as Plaintiffs' state law claims seek to do. These points merit reconsideration.

A. Legal Standard

Local Civil Rule 7.1(i) allows reconsideration of matters the Court has "overlooked" that "may alter the disposition of the matter." *K.J. v. Greater Egg Harbor Reg'l High Sch. Dist. Bd. of Educ.*, No. CV 14-145, 2020 WL 3542305, at *1 (D.N.J. June 30, 2020). Defendants may satisfy this "high" standard by demonstrating "the need to correct a clear error of law or fact or to prevent manifest injustice." *Id*. (internal citation omitted). Reconsideration is appropriate on "clear error" grounds "if a court 'overlooks' controlling law." *Estate of Del Rosario by Gonzalez v. Paterson Police Dep't*, No. CV 14-5167, 2017 WL 1050572, at *1 (D.N.J. Mar. 20, 2017). Defendants submit that is the case here.

B. The Court Overlooked and Misapprehended U.S. Supreme Court Precedent

Contrary to the Opinion, *Wyeth* is not the "latest" or most "on-point" case applicable here. *Buckman* and *Wyeth* represent separate lines of preemption

authority addressed to distinct issues. Indeed, Plaintiffs' own opposition cited *Wyeth* for only two limited purposes—to assert a presumption against preemption and to argue against "impossibility preemption." (*See* ECF Doc. 577 at 39-40). Plaintiffs did not assert *Wyeth* in answer to *Buckman* because *Buckman* addresses a separate subject: preemption of a state law claim that violates Section 337(a)'s requirement that all proceedings "for the enforcement" of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a).

Buckman considered preemption of an alleged state law claim for fraudulent representations to the Food & Drug Administration ("FDA") in obtaining approval to market bone screws. 531 U.S. at 344. The Court found this "fraud-on-the-FDA" claim preempted because plaintiffs' claims "would not be relying on traditional state tort law" predating the "federal enactments in question," but rather "the existence of these federal enactments is a critical element in their case" and the claims "exist solely by virtue of" the FDCA's requirements. *Id*. at 353. The Court found such a claim preempted as an impermissible attempt to privately enforce the FDCA under the guise of state law in violation of Section 337(a).

Wyeth, conversely, considered whether FDA approval of a label provides a "complete defense" to state law failure-to-warn claims. 555 U.S. at 558. The Court concluded that, under the circumstances of that case, "impossibility" and "obstacle" preemption did not preempt a failure-to-warn claim against a brand manufacturer.

Id. at 568-81. The *Wyeth* majority mentioned *Buckman* only once, in a footnote stating that *Buckman* did not preclude applying a presumption against preemption in a case involving traditional "state regulation of health and safety[.]" *Id*. at 565 n.3. The majority did not discuss *Buckman*'s preemption under Secton 337(a) of state law claims depending on the FDCA for their existence. *Wyeth* leaves that holding and its underlying reasoning untouched.

Multiple subsequent rulings by the Supreme Court have only sharpened the distinction between the two lines of authority. The Court has revisited *Wyeth* at least three times in the pharmaceutical context with scarcely a reference to *Buckman*. In *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617-26 (2011), the Court distinguished *Wyeth*, which involved claims against a brand manufacturer, and held state law failure-to-warn claims against *generic* drug manufacturers *are* preempted because generic drugs are subject to a federal "duty of sameness" prohibiting changes to their warning labels. The Court referenced *Buckman* only in passing, noting that a claim "based on failure to properly communicate with the FDA" would run afoul of *Buckman*. *Id*. at 619. In *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472, 479-93 (2013), the Court extended *Mensing* preemption to defective design and "stop selling" claims, again distinguishing *Wyeth* as inapposite outside of the context of a failure-to-warn claim against a brand manufacturer—with no discussion of *Buckman*. And in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672,

1676-80 (2019), the Court revisited *Wyeth* to explain what proof is required to establish preemption through "clear evidence" that FDA would have rejected a brand manufacturer's label change, again with no mention of *Buckman*.

As Judge Rosenberg found in granting dismissal on preemption grounds in *In re Zantac* (albeit with leave to amend certain claims), *Wyeth*'s implications are limited to failure-to-warn claims against brand manufacturers, whereas *Mensing* and *Bartlett* supply a different impossibility preemption framework for claims against generic manufacturers and other entities that do not hold the NDA for the drug. *In re Zantac*, ECF Doc. 2512 at 14-19, ECF Doc. 2513 at 13-19.[1] None of these rulings, moreover, purport to address preemption under Section 337(a) or *Buckman*.

The Supreme Court's subsequent discussions of *Buckman* since *Wyeth* have likewise reiterated the central point that all claims threatening to disrupt the FDCA's exclusive enforcement regime are preempted. *See Kansas v. Garcia*, 140 S. Ct. 791, 807 (2020) (distinguishing *Buckman* because it involved a claim that "threatened serious disruption" of FDCA scheme); *Chamber of Commerce of the United States v. Whiting*, 563 U.S. 582, 604 (2011) (distinguishing *Buckman* because it involved a "uniquely federal area[] of regulation" and concerned "state actions that directly

[1] Copies of the two *In re Zantac* rulings are attached hereto as **Exhibits A and B**. Though the Opinion notes the absence of a citation to *Wyeth* in Defendants' brief (Opinion at 10), it should be noted that Defendants did cite and discuss *Mensing* and *Bartlett*. (*See* ECF Doc. 520-3 at 38-39 n.35).

interfered with the operation of the federal program").

Preemption under *Buckman* is thus unaffected by *Wyeth* and applies here. As discussed in Defendants' opening brief, "the existence" of the FDCA "is a critical element" of each claim and each claim "exist[s] solely by virtue of" the FDCA. (*See* ECF Doc. 520-3, at 18-27 & notes 16-18, 21, 23, 26, 27; *Buckman*, 531 U.S. at 352-53). The Opinion's finding that Plaintiffs' claims are not preempted because they "depend on traditional tort and contract law sources and not on a 'fraud-on-the-FDA claim" misses the crux of Defendants' preemption argument. (Op. at 12). Even the cases in the *Wyeth* line, as well as *In re Zantac*, make clear a state law claim can "depend on traditional tort and contract law sources" and still be preempted. *See, e.g.*, *Mensing*, 564 U.S. at 617-19 (holding state-law failure-to-warn claim preempted); *Bartlett*, 570 U.S. at 476 (holding state-law design-defect claims preempted); *In re Zantac*, ECF Doc. 2512 at 17-19 (collecting cases holding state-law tort and contract claims preempted). And the *Buckman* line further confirms that efforts to enforce exclusively federal requirements through the assertion of state law claims that depend on FDCA requirements and exist solely by virtue of the FDCA are preempted regardless of their alleged dependence on traditional state causes of action. The Court should therefore reconsider its Opinion and Order.

C. The Court Overlooked the Weight of Authority in Confining *Buckman* Solely to "Fraud-on-the-FDA" Claims

The Opinion also errs in holding based on *Tigert* and *Desiano v. Warner-*

Lambert & Co., 467 F.3d 85 (2d Cir. 2006), that *Buckman* is limited to "fraud-on-the-FDA" claims. (Op. at 11-12). *Tigert* and *Desiano* represent the minority view, while a preponderance of well-reasoned authority supports the contrary view that *Buckman* extends to any attempt to enforce the FDCA's exclusively federal requirements under the semblance of a state law claim. Notably, Plaintiffs did not cite *Tigert* or *Desiano* in opposing Defendants' motions to dismiss.

Buckman declares that Section 337(a) "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with" the FDCA's requirements. 531 U.S. at 349 n.4. The majority view holds that this mechanism "is thwarted if savvy plaintiffs can label as arising under a state law" a claim "that in substance seeks to enforce the FDCA." *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579 (6th Cir. 2013); *see also Exela Pharma Scis., LLC v. Sandoz Inc.*, No. 1:19-CV-00318-MR, 2020 WL 5535026, at *5 (W.D.N.C. Sept. 15, 2020) (same); *Borchenko v. L'Oreal USA, Inc.*, 389 F.Supp.3d 769, 773 (C.D. Cal. 2019). "Thus, where private litigants are effectively suing for a violation of the FDCA under the guise of state law, their claims are impliedly preempted." *Evans v. Rich*, No. 5:13-CV-868-BO, 2014 WL 2535221, at *2 (E.D.N.C. June 5, 2014); *see also Riley v. Cordis Corp.*, 625 F.Supp.2d 769, 777 (D. Minn. 2009) (holding *Buckman* preempts a state-law claim that "is in substance (even if not in form) a claim for violating the FDCA"). Or, as the Third Circuit has

expressed it, *Buckman* "center[s] on potential state interference with a federal agency." *Golden v. N.J. Inst. of Tech.*, 934 F.3d 302, 310 (3d Cir. 2019).

The test for *Buckman* preemption "is whether or not the claim would exist in the absence of the FDCA." *Evans*, 2014 WL 2535221, at *2 (citing *Loreto*, 515 Fed. App'x at 579). Any claim "that relies on the FDCA or its implementing regulations '[a]s a critical element' is barred by § 337(a).'" *Agee v. Alphatec Spine, Inc.*, No. 1:15-CV-750, 2017 WL 5706002, at *3 (S.D. Ohio Mar. 27, 2017) (quoting *Marsh v. Genentech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012)).[2] That includes "traditional" claims. *See, e.g., In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 936 (6th Cir. 2014) (negligence per se); *Perez v. Nidek Co.*, 711 F.3d 1109, 1119-20 (9th Cir. 2013) (fraud); *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1205-06 (8th Cir. 2010) (failure to report); *Nexus Pharm., Inc. v. Quva Pharma, Inc.*, No. CV2007518CJCJDEX, 2020 WL 6498970, at *3 (C.D. Cal. Oct. 29, 2020) (unfair competition); *In re Medtronic, Inc. Sprint Fidelis Leads Products Liab. Litig.*, 592 F.Supp.2d 1147, 1159-64 (D. Minn. 2009) (multiple claims); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*,

[2] These cases align with FDA's views in its *amicus* brief in *Amarin Pharma, Inc. v. ITC* (Fed. Cir. Mar. 27, 2018) (2018-1247, 2018-114) ("FDA Amicus"), cited in Defendants' opening brief. (*See* ECF Doc. 520-3 at 18-19, 26). The Opinion notes *Wyeth*'s statement that the Court does not defer to a "throwaway" statement by FDA regarding preemption. (Opinion at 11 (quoting *Wyeth*, 555 U.S. at 578)). The FDA Amicus, however, is no "throwaway" statement; it is a thorough, consistent, and persuasive interpretation of the import of Section 337(a).

590 F.Supp.2d 1282, 1290-91 (C.D. Cal. 2008) (unfair competition).

The Second Circuit's ruling in *Desiano*, on which this Court relied in *Tigert* and the Opinion, is the minority view. *Desiano* split from the Sixth Circuit in *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004), and distinguished *Buckman* in the limited context of a state law affirmative defense. 467 F.3d at 93-97. The Third Circuit has since distinguished *Desiano* insofar as it "pre-date[s] the Supreme Court's *Mensing* and *Bartlett* decisions" and "address[es] preemption in the context of claims against manufacturers of branded, not generic, drugs." *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II)*, 751 F.3d 150, 160 (3d Cir. 2014). And the Fifth, Eighth, and Ninth Circuits have either expressly rejected *Desiano* or adopted a broader view of *Buckman*. *See Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d 372, 377-80 (5th Cir. 2012) (finding *Desiano* "unpersuasive" and the Sixth Circuit's approach "more faithful to *Buckman*," and noting that *Wyeth* did not "cut back on" *Buckman*); *Perez*, 711 F.3d at 1119-20; *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d at 1205-06; *see also Marsh*, 693 F.3d at 551 n.6.[3] Unlike *Tigert*, moreover, Plaintiffs' claims here

[3] Numerous district courts have also adopted the broader view of *Buckman*. *See In re Depakote*, No. 12-CV-52-NJR-SCW, 2017 WL 4348052, at *7 (S.D. Ill. Sept. 28, 2017); *Estate of Muniz v. Genentech, Inc.*, No. 1:11-CV-683, 2011 WL 5089289, at *5 (W.D. Mich. Oct. 26, 2011); *Shannon v. Johnson & Johnson*, No. 1:09 OE 40043, 2011 WL 2471921, at *4 (N.D. Ohio June 21, 2011); *In re Trasylol Prod. Liab. Litig.*, 763 F. Supp. 2d 1312, 1325 (S.D. Fla. 2010); *In re Baycol Prod. Litig.*, No. 04-3667, 2009 WL 7836091, at *3 n.1 (D. Minn. Feb. 13, 2009).

raise the "decisive factor[]" behind *Buckman* preemption—private enforcement of the FDCA. 2012 WL 6596806, at *4-5.

The Opinion states incorrectly that Defendants' "arguments for preemption rest chiefly on their re-formulation of these tort claims at issue as somehow fraud-on-the-FDA claims in disguise." (Op. at 12). Respectfully, that is not Defendants' argument. Rather, each of the claims at issue facially relies on the FDCA and its regulations and could not exist in their absence. (*See* ECF Doc. 520-3, at 18-27 & notes 16-18, 21, 23, 26, 27). Plaintiffs' claims thus seek to privately enforce the FDCA, are barred by Section 337(a) and preempted under *Buckman*.[4]

D. The Court Erred in Holding the Act Does Not Expressly Preempt Plaintiffs' Claims Against Wholesalers and Pharmacies.

The Opinion further errs in its analysis of express preemption under the Act.

First, the Opinion rejects a preemption finding as to the Wholesalers and Pharmacies because such a finding would "preclude courts from affording state consumers any protection from defective drugs." (Op. at 14). However, the fact that preemption may leave some individuals without a remedy against some defendants

[4] The Opinion also misstates Plaintiffs' allegations that the VCDs at issue "contained nitrosamines, known carcinogens." (Opinion at 3). Plaintiffs only allege that nitrosamines are "probable" carcinogens in humans. *See, e.g.*, ELMC ¶ 317; MMMC ¶ 280; PIMC ¶¶ 157. FDA has explained nitrosamines are "common in water and foods," with potential carcinogenic effects depending on level and duration of exposure. *See* FDA Provides Guidance to Industry for Detecting and Preventing Nitrosamines in Drugs, available at https://tinyurl.com/y9bsdzto.

is no basis to refuse preemption. *See Mensing*, 564 U.S. at 625. Moreover, the Court overlooks the fact that *only* the Wholesalers and Pharmacies moved to dismiss under the Act because they are the only entities subject to the Act's requirements to refuse a product absent the transaction information specified by Congress. (*See* ECF Doc. 599 at 17-18; Doc. 522 at 10-13).[5] The Manufacturers did *not* move under the Act because they are not subject to the same "product tracing" duties imposed upon the Wholesalers and Pharmacies. Thus, there is no viable concern regarding absence of remedy to support the Court's refusal of preemption.

Second, the Opinion's analysis of the Act's savings clause (Op. at 14), overlooks the operative phrase, "product tracing as described in subsection (a)."[6] The test is not whether Plaintiffs' claims "arise out of any defective tracing" (*id.* at 15), but whether Plaintiffs' claims impose requirements that are more stringent than the requirements described in subsection (a) of the Act. (*See* ECF Doc. 599 at 19).

Finally, the Opinion relies heavily on a "presumption against preemption." (*See* Op. at 12) (citing *Farina v. Nokia, Inc.*, 625 F.3d 97, 115 (3d Cir. 2010). But

[5] As explained in *In re Zantac*, the Act imposes specific obligations on downstream defendants: "the Act creates a comprehensive, national framework that sets pharmacies' requirements for identifying, tracing, and isolating adulterated or misbranded drugs." *See id.*, ECF Doc. 2513, at 40.

[6] The *Zantac* Court rejected reliance on the savings clause, finding plaintiffs "ignore[d]" the "additional text in the statute" and holding the Act "preempts requirements pertaining to transaction statements, certification, investigation, or record keeping," as set forth in subsection (a). *See id.*, ECF Doc. 2513 at 41-42.

Farina and similar cases must be reconsidered in light of recent Supreme Court authority. The Court's "inquiry into the scope of a [federal] statute's pre-emptive effect is guided by the rule that the purpose of Congress is the ultimate touchstone in every pre-emption case." *Hughes v. Talen Energy Mktg., LLC*, 136 S.Ct. 1288, 1297 (2016). No presumption against preemption attaches in the face of the "plain wording" of an express preemption clause. *Puerto Rico v. Franklin Cal. Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016).[7] The plain wording of the Act preempts plaintiffs' claims against the Wholesalers and Retailers.

II. Alternatively, the Court Should Grant Section 1292(b) Certification

Defendants alternatively request that the Court enter a written certification that the Opinion and Order involve "a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b). Defendants bear the burden of demonstrating the accuracy of the requested certification. *Meyers v. Heffernan*, No. CIV.A. 12-2434 MLC, 2014 WL 7336792, at *3 (D.N.J. Dec. 22, 2014) (citations omitted). The purpose of certification is "to permit decision of legal issues as to which there is considerable

[7] *See also Coventry Health Care of Mo., Inc. v. Nevils*, 137 S. Ct. 1190, 1197-98 & n.3 (2017); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315–30 (2008); *Atay v. County of Maui*, 842 F.3d 688, 699 (9th Cir. 2016); *Watson v. Air Methods Corp.*, 870 F.3d 812, 817 (8th Cir. 2017).

question," while avoiding "possibly wasted trial time and litigation expense." *Id*. (quoting *P. Schoenfeld Asset Mgmt. LLC v. Cendant Corp.*, 161 F.Supp.2d 355, 358 (D.N.J. 2001); *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 756 (3d Cir. 1974)).

The Opinion and Order present "controlling questions of law" because "if erroneous" they "would be reversible error on final appeal.'" *Meyers*, 2014 WL 7336792, at *4 (quoting *Katz*, 496 F.2d at 755; *P. Schoenfeld Asset Mgmt.*, 161 F.Supp.2d at 358). If the Opinion and Order are in error as to preemption under *Buckman* or the Act, it requires either dismissal of six claims against all Defendants or dismissal of all claims against the Wholesalers and Retailers, or both.

The Opinion and Order also present substantial grounds for a difference of opinion, which "must arise out of genuine doubt as to the correct legal standard." *Meyers*, 2014 WL 7336792, at *4 (quoting *P. Schoenfeld Asset Mgmt.*, 161 F.Supp.2d at 360; *Kapossy v. McGraw-Hill, Inc.*, 942 F.Supp. 996, 1001 (D.N.J. 1996)). Such doubt can stem from, *inter alia*, "conflicting precedent, the absence of controlling law on a particular issue, or novel and complex issues of statutory interpretation." *Id*. (quoting *Litgo New Jersey, Inc. v. Martin*, No.CIV. 06-2891 AET, 2011 WL 1134676, at *3 (D.N.J. Mar. 25, 2011)). Here, as discussed in § I.C, *supra*, the *Buckman* preemption question concerns an issue on which circuits are split (with the Opinion on the minority side of the issue), while preemption under the Act involves what the Opinion itself acknowledges is "a matter of first

impression" in this Circuit and this District. (Op. at 14).

Finally, an interlocutory appeal would materially advance the ultimate termination of this litigation. Section 1292(b) certification "materially advances the ultimate termination of the litigation" where the appeal "eliminates: (1) the need for trial; (2) complex issues that would complicate the trial; or (3) issues that would make discovery more costly or burdensome." *Litgo*, 2011 WL 7336792, at *3 (citing *New Jersey, Dept. of Treasury v. Fuld*, Civ. No. 09-1629 (AET), 2009 WL 2905432, at *2 (D.N.J. Sept. 8, 2009)). In this case, the outcome of the preemption question will not just impact the need for one trial, but potentially every trial in this MDL, as well as the potential success of any resolution efforts. Even if claims remain to be tried after the appeal, the outcome of the appeal could greatly streamline and simplify the claims, issues, discovery, and parties remaining. An appeal now would potentially save millions of dollars, thousands of hours, and years of needless litigation on claims that substantial authority indicates are subject to dismissal.

III. CONCLUSION

For these reasons, Defendants respectfully request that the Court enter an Order: (1) reconsidering its Opinion and Order and dismissing Plaintiffs' claims on federal preemption grounds under Section 337(a) of the FDCA, *Buckman*, and the Act; (2) in the alternative, granting Section 1292(b) certification; and (3) granting such other and further relief as the Court deems necessary or appropriate.

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Respectfully submitted,

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